UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/523,076	01/25/2005	Hiroyuki Tokunaga	2005_0071A	8391

52349 7590 11/30/2007

WENDEROTH, LIND & PONACK L.L.P.
2033 K. STREET, NW
SUITE 800
WASHINGTON, DC 20006

EXAMINER	
OLSEN, KAJ K	

ART UNIT	PAPER NUMBER
1795	

MAIL DATE	DELIVERY MODE
11/30/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/523,076	TOKUNAGA ET AL.	
	Examiner	Art Unit	
	Kaj K. Olsen	1795	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 October 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *3-22-05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election of 10-29-2007 is acknowledged. However, this examiner is withdrawing the previous election requirement and is examining all the claims irrespective of the elected species.

Specification

2. The disclosure is objected to because of the following informalities: The specification must open with a paragraph stating that this application is a 371 National Stage entry of PCT/JP 03/13991, filed on 10/31/2003.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 6-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5. In claim 6, the limitation beginning "it is discriminated" is passive and should be replaced with a more explicit recitation of the step of discriminating between the sample and standard solutions.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1-5 are rejected under 35 U.S.C. 102(b) as being anticipated by Nankai et al (USP 5,120,420).

8. With respect to claims 1 and 5, Nankai discloses a standard solution that includes absorbic acid (col. 9, ll. 31-54), which the applicant evidences is a reducing substance (see claim 5). With respect to limitations drawn to the measuring apparatus itself, it is noted that the measurement apparatus is only the intended use of the apparatus and the intended use need not be given further due consideration in determining patentability. Claim 1 is drawn to a standard solution that is "used for controlling a precision of measurement of a measurement apparatus". Hence, the measurement apparatus is not being claimed and doesn't further define the claimed standard solution itself. However, it is noted that Nankai does appear to disclose all the elements of the set forth measurement apparatus. See fig. 4 and col. 4, l. 41 through col. 5, l. 29.

9. With respect to claim 2, how the unclaimed measurement apparatus is to be utilized also does not further define the actually claimed standard solution.

10. With respect to claim 3, because the ascorbic acid of Nankai is one of the same reducing substances utilized by the instant invention, it inherently would provide a larger value of oxidation current during any first potential in comparison with a second potential. With respect to actually applying any first or second potentials, how the unclaimed measurement apparatus is to be utilized does not further define the actually claimed standard solution.

11. With respect to claim 4, Nankai evidences that ascorbic acid provides an oxidation current with 0.6 V. See col. 10, ll. 21-29.

12. Claims 1-4 are rejected under 35 U.S.C. 102(b) as being anticipated by Ye (USP 5,723,284).

13. Ye discloses a control solution (i.e. standard solution) containing a mediator, such as ferricyanide, which at least partially exists as the reducing substance ferrocyanide. See col. 5, l. 45 through col. 6, l. 52. Hence, the portion of the control solution that exists as the reduced ferrocyanide would read on the defined reducing substance of the claims. Moreover, fig. 1 evidences that a component in the control solution is undergoing oxidation (i.e. a reducing substance) because the control solution is providing a positive oxidation current during the burn period. This is presumably the residual reduced form of the mediator present in the control solution. With respect to the details of the measurement apparatus or how the measurement apparatus is to be utilized, as discussed above for Nankai, that is only the intended use of the standard solution and the intended use need not be given further due consideration in determining patentability. However, see the 103 rejection below.

14. With respect to the reducing substance being oxidized at the set forth potentials, the burn voltage of Ye utilized for generating the oxidized current is 0.4 V (col. 7, ll. 44-55) evidencing

that the reduced form of the mediator (i.e. reducing substance) is oxidized within the claimed range.

Claim Rejections - 35 USC § 103

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

16. Claims 6, 7, 9, and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ye in view of WO 02/44705 (hereafter "WO '705"). For the discussion of WO '705, the examiner will be relying on the English language disclosure of Miyazaki et al (USP 7,232,510). All cited text for WO '705 refers to the text from Miyazaki.

17. With respect to claim 6, Ye discloses a method for determining a substance (glucose) contained in a sample solution (whole blood) on the basis of an oxidation current value which is obtained by applying a first potential by a driving power supply (i.e. the burn potential) to an electrode portion of a biosensor having a working electrode and a counter electrode (i.e. reference electrode), a reagent layer reacting with the sample solution supplied to the electrode portion for a first time period (i.e. the burn period), then stopping the application for a given time period (i.e. the wait period), and applying a second potential for second time period (i.e. the read period). See fig. 1, col. 4, ll. 15-28 and col. 7, l. 44 through col. 8, l. 3. As discussed above in the 102 rejection, Ye further discloses the use of a standard solution (i.e. control solution) containing a reducing substance (i.e. the reduced form of the mediator) for controlling the

precision of the measurement and the sample and control solutions are discriminated from each other on the basis of the oxidation current value obtained by applying the first potential and the oxidation current value obtained by applying the second potential. In particular, Ye notes that the control substance has a higher read to burn (R/B) ratio and the discrimination relies on the observance of a higher R/B ratio. See col. 6, ll. 38-47. Ye did not explicitly disclose that the second potential is smaller than the first potential. WO '705 discloses the use of a burn voltage V1 that exceeds the read voltage V2 and indicates that this choice of higher V1 with subsequently lower V2 was motivated by the desired balance between reaction product consumption and reaction speed during the burn period with the desire to apply a V2 only high enough to oxidize the ferrocyanide. See fig. 9 and col. 14, l. 65 through col. 15, l. 39. It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of WO '705 and utilize a read voltage that is smaller than the burn voltage for the method of Ye in order to provide voltage levels that better balance the different goals of the burn and read periods.

18. With respect to claim 7, the oxidation current during the first potential is "definitely different" from that of the sample whereas during the read period they are "similar", giving the claim language its broadest reasonable interpretation. See fig. 1 of Ye.

19. With respect to claim 9, see Ye, col. 6, ll. 21-47.

20. With respect to claim 11, the burn voltage of Ye utilized for generating the oxidized current is 0.4 V (col. 7, ll. 44-55) evidencing that the reduced form of the mediator (i.e. reducing substance) is oxidized within the claimed range.

21. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ye in view of WO '705 as applied to claim 6 above, and further in view of EP 1 156 324 (hereafter "EP '324").

22. The references set forth all the limitations of the claim, but did not explicitly disclose the use of the set forth discrimination function. EP '324 discloses in an alternate method for differentiating standard solutions from sample solutions and teaches the use of a discrimination function employing a discrimination parameter as an independent variable whereby a value is input into the discrimination function to be taken as a discrimination index. See paragraphs 0027-0057. Because a discrimination index provides a convenient computation means for deciphering whether a given measurement is sample or standard, it would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize known computational means as disclosed by EP '324 to analyze the method of Ye and WO '705 to yield the predictable result of having the sample measurement differentiated from the standard measurements.

Allowable Subject Matter

23. Claims 8 and 12 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

24. The following is a statement of reasons for the indication of allowable subject matter: With respect to claim 8, the prior art does not disclose nor render obvious all the cumulative limitations of claims 6 and 8 with particular attention to where the value of the oxidation current which flows when the first potential is applied is larger than the value of the oxidation current

which flows when the second potential is applied. In particular, this is the opposite of the teaching of Ye which teaches suppressing the current during the first potential for the standard solution so as to make the R/B ratio for the standard larger than that for the sample. See fig. 1 as an example. With respect to claim 12, the prior art does not disclose nor render obvious all the cumulative limitations of claim 6 where the reducing substance is one of the set forth components of claim 12.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kaj Olsen whose telephone number is (571) 272-1344. The examiner can normally be reached on Monday through Friday from 8:00 A.M. to 4:30 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nam Nguyen, can be reached on 571-272-1342. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

AU 1795

11/28/07

KAJ K. OLSEN
PRIMARY EXAMINER